DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5, 7-8, 15-19, 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has failed to provide support within the written specification, as originally filed, for the newly added claim limitation, "and wherein a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers" in combination with the other claimed elements. Applicant's specification makes no mention of the beat frequency signal being configured to avoid remaining in and shunting through CSF proximate to the subject's spinal cord.

3. Applicant alleges support for the newly added claim limitation based on the following cited specification passages: page 2, lines 11-21, page 3, lines 15-23, and page 6, lines 15-20.

4. Page 2, lines 11-21 are directed to a background section discussing conventional spinal cord stimulation systems that do not use interferential stimulation and states, "most of the current remains in the CSF." Examiner considers this to be a statement with regard to the current state of the prior art, but in no way does this passage convey support that Applicant's invention will provide for "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers."

5. Page 3, lines 15-23 state;

> "The amplitude can be, modulated in the respective circuits to increase the area of targeted stimulation. This type of current (Interferential) provides improved directional control, decreased accommodation / habituation and increased depth of penetration in comparison to other standard implantable stimulation systems and their accompanying surgical leads. The amplitudes of the outputs in the respective circuits may be modulated to increase the area of targeted stimulation. Interferential current allows improved directional control and depth of penetration in comparison to other stimulation techniques."

6. Examiner considers the above passage to simply teach the benefit of interferential stimulation for providing increased directional control and depth of penetration. In no way does the above passage implicitly or explicitly disclose "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and

shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." It is unclear how the above passage can be read to imply any affect of the beat frequency avoiding remaining within and shunting through CSF when there is no mention of the CSF affect at all in the above passage.

7. Page 6, lines 15-20 state;

> "The digital signal processor 102 improves the accuracy and reliability of digital signals. The digital signal processor 102 processes the multiple pulses 116 from the signal generating source 104 to approximate a sine-wave (pseudo-sine-wave or sine-wave-like). Thus, that type of current recruits larger numbers of dorsal column fibers and provides greater levels of pain relief."

8. Examiner considers the above passage to teach only that a sine-wave/pseudo-sine-wave/sine-wave like signal recruits larger numbers of dorsal column fibers and provides greater levels of pain relief. The above passage fails to implicitly or explicitly disclose in any way that "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." The above passage makes no mention of the beat frequency let alone the beat frequency being directed to avoid remaining in and shunting through the CSF.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-5, 7-8, 15-19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss (US 5,512,057) in view of Holsheimer et al. (US 5,643,330).

11. Reiss discloses an interferential spinal cord stimulation system with at least two pairs of electrodes (e.g. Fig. 1 and Col. 3, line 35-39), a sinusoidal pulse generator (e.g. Col. 2, line 13), stimulation frequencies greater than 500hz and less than 20Khz, and wherein the electrode pairs create a beat frequency proximate the subject's spinal cord (e.g. Col. 2, line 3-17).

12. Reiss fails to explicitly teach the use of implantable electrodes. Holsheimer teaches that it is known to use electrodes implanted to the dura matter for use in interferential spinal cord stimulation as set forth in ABSTRACT for providing the predictable results of decreasing power consumption by placing the electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss with electrodes implanted to the dura matter since such a modification

would provide the predictable results of as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients.

13. Examiner considers the invention as taught by Reiss in view of Holsheimer to sufficiently meet applicant's newly added claim limitations of "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers" since Reiss in view of Holsheimer teach a system for interferential stimulation with implanted electrodes and meet all claimed stimulation parameter limitations, so therefore Examiner considers the system as taught by Reiss in view of Holsheimer to be capable of providing that "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers."

14. With regard to claim 2, Reiss discloses a digital to analog circuit associated with the microcontroller for generating digital signal pulses (e.g. Fig. 5B).

15. With regard to claim 3, Reiss discloses a programmable gate array integrated circuit (e.g. Col. 4, line 47-65).

16. With regard to claim 4, Reiss discloses the beat frequency is optimally only 200Hz (e.g. Col. 2, line 3-17).

17. With regard to claim 5, Reiss discloses no more than 11 volts being outputted (e.g. Col. 4, line 3-9).

18. With regard to claim 7, Reiss discloses the pulse width of the interferential signal to be no more than 500 microseconds (e.g. Col. 2, line 3-17).

19. With regard to claim 8 and 22, Reiss in view of Holsheimer disclose the invention as claimed but fail to explicitly teach the use of quadripolar electrodes. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss in view of Holsheimer with use of quadripolar electrodes since such a modification would provide the predictable results of effective and efficient stimulation as well as facilitating controlling and directing the interferential field to the target site.

Response to Amendment

20. The Declaration under 37 CFR 1.132 filed 3/29/2011 is insufficient to overcome the rejection of claim1-5, 7-8, 15-19, 21-22 based upon Reiss in view of Holsheimer as set forth in the last Office action because: Examiner considers the current Declaration filed 3/29/2011 to further support the declaration filed 11/14/2008. In light of the 3/29/2011 Declaration, Examiner considers Declaration filed 11/14/2008 to support showing implanted electrodes within the Dura and epidural space, which do not further limit the scope by implanting stimulation electrodes directly on the pyramidal tract and gracilie nucleus. The 3/29/2011 Declaration appears to show that modification of Reiss in view of Holsheimer would not be obvious for the purpose of achieving a greater depth of penetration, however fails to discredit implantation of electrodes in combination with the discloses system of Reiss for any other purpose (i.e. ensuring/maintaining proper placement of electrodes for chronic stimulation patients).

Response to Arguments

21. Applicant's arguments filed 3/29/2011 have been fully considered but they are not persuasive.

22. Applicant argues support for the claim limitation, "avoid remaining in and shunting through CSF." Examiner acknowledges proper support for the limitations, "directionally distributed and controlled" and "recruiting dorsal column fibers" but there is no mention that Applicant's claimed invention actually avoids remaining in and shunting through CSF. The only mention of anything remotely close to this is a statement of the prior art failures, but the statement of the prior arts failures and shortcomings is not equivalent to stating the claimed invention will avoid remaining in and shunting through CSF.

23. Applicant argues the Yearwood Declaration filed 3/29/2011 supports the claim limitation in question and alleges opinion testimony which purports to state that a particular feature or limitation of a claim is disclosed in an application and explains the underlying factual basis for the opinion must be considered. Examiner respectfully disagrees. Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. In re Buchner, 929 F.2d 660, 18 USPQ2d 1331 (Fed Cir. 1991).

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joseph Stoklosa
Examiner
Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762
5/20/2011

/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762